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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 07-01)

Office Action Summary	Application No.	Applicant(s)	
	09/834,700	BRAUN, ANDREAS	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11-20,44-53,69-71 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,11-20,44-53,69-71 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *0203* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed February 5, 2003. Currently, claims 1-8, 11-20, 44-53, 69-71, 75 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I in Paper filed February 5, 2003 is acknowledged.

Oath/Declaration

3. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because the oath claims benefit under 120 for two provisional applications. Provisional applications are entitled to benefit under 119(e). Therefore, the oath is not proper.

Priority

4. This application claims priority to two provisional applications.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The instant specification contains a large paragraph discussing related applications, however never

specifically asserts whether priority is being claimed. Benefit claims under 35 U.S.C. 119(e) must include a specific reference to the earlier filed provisional application for which a benefit is sought. Moreover, Benefit claims under 35 U.S.C. 120 must include a specific reference to the earlier filed (nonprovisional) application for which a benefit is sought. A "specific reference" requires: (1) the identification of the prior (nonprovisional) application by application number; and (2) an indication of the relationship between the nonprovisional applications. There is no specific relationship provided between the applications. Appropriate correction and clarification is required.

Specification

5. The disclosure is objected to because of the following informalities.

On page 99 of the specification, line 2, there is a cite to a PNAS reference. It appears as though the publication date of the reference should be 1997 rather than 1007.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 1-8, 11-20, 44-53, 69-71, 75 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a substantial asserted utility or a well established utility.

The claims are drawn to an isolated nucleic acid molecule comprising a sequence of nucleotides that encodes a polypeptide as set forth in SEQ ID NO: 2 except at position 646 of SEQ ID NO: 2, Ile is substituted with Val, Leu or Phe. The claims are also drawn to primer, probes hybridizing to SEQ ID NO: 1 and at least 14 contiguous nucleotides from SEQ ID NO: 3 wherein at least 5 contiguous nucleotides are set forth in positions 2069-2077 of SEQ ID NO: 3.

The specification teaches that AKAP10 is located on Chromosome 17, contains 15 exons and 14 exons and has been found to be responsible for the sub-cellular localization of the camp-dependent protein kinase (page 98, lines 28-32). The art teaches the AKAP10 cDNA (D-AKAP2) in Genbank Accession Number AF037439 and NM007202 (page 41). The specification teaches the detection of a single polymorphisms within the AKAP10 protein which causes a substitution of a Ile to a Val at position 646 of SEQ ID NO: 2 and a substitution of an A to a G at position 2073 of SEQ ID NO: 1. The specification asserts that the allelic variant has been found to vary in frequency in DNA samples from younger and older segments of a healthy population (page 43, lines 5-10). The specification similarly discusses AKAP10-1 allele which is located in the 3'UTR region. The specification performed similarly studies with regard to age related polymorphisms and determined that there was a difference between the populations.

The art teachesD-AKAP2 is a novel protein kinase A anchoring protein with a putative RGS domain. The cloning of a novel AKAP which interacts with both the type I

and II regulatory subunits was reported as D-AKAP2 (Huang et al. PNAS, Vol. 94, pages 11184-111889, October 1997).

The specification nor the art has taught a substantial utility for a nucleic acid variant which comprises a single nucleotide polymorphism at position 2073 of SEQ ID NO: 3 which causes a substitution in the amino acid sequence at position 646. A substantial utility is defined as a utility that defines a "real world" us such that the utilities do not require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use. The specification asserts that the nucleic acid is useful to determine increased or early susceptibility to morbidity. This assertion is not substantial because further research to identify or reasonably confirm a "real world" context of use would be required.

The specification does not appear to support the conclusion that the AKAP10-5 G allele is associated with "increased susceptibility to morbidity, increased or early mortality, or morbidity and increased or early mortality as compared to the susceptibility of a subject who does not comprise the allelic variant" (page 15). The study performed in the specification was performed using healthy samples through the blood bank of California. The donors were of Caucasian origin. The specification asserts that a healthy subject is defined as human donor who passes blood bank criteria to donate blood. An analysis of data is presented in Table 4 stratified by males and females by age groups (page 103-104). The data does not appear to suggest that there is an increase susceptibility to morbidity because in males who are heterozygous for GA at position 2073 of SEQ ID NO: 1, more "older" individuals than "younger" individuals are

found. Therefore, the assertion that the presence of a G increases susceptibility does not appear to be consistent with the ~~date~~ data. The data provides that 45.9% of younger individuals have GA whereas 52.5% of older individuals have GA. Therefore, the ~~date~~ data with respect to men does not appear to support the conclusion. Additionally, for the combined sexes, the data also suggests that GA individuals are very slightly more likely to be found in older populations. 47.7% vs 49.4% were found in younger and older populations respectively to have the GA herterozygosity. Therefore, the conclusion that the variant G allele is associated with increased susceptibility to morbidity does not appear to be supported by the data. When considering the pure analysis of G and A alleles, the minimal difference of 4.1% between young and old populations would require the researcher to further analyze the information to determine whether the polymorphism was meaningful. Give the information in Table 3, using a statistical calculation website to determine the 2x2 contingency table, the p-value provided by the website was p=.13 which is not statistically significant.

JA 5/1/03

gttp://faculty.vassar.edu/lowry/odds2x2.html

It is additionally noted that the specification fails to study an ethnically diverse population. The specification states that only Caucasian individuals were analyzed and a very minimal difference was found. The specification teaches a mere difference of 60 and 64% between the two populations. The skilled artisan would be required to perform additional experimentation to determine whether this particular population is representative of the entire world population or whether this was merely applicable to Caucasian individuals.

The specification does not analyze individuals in a progressive study of their lifetime but rather takes a current snapshot of the percent frequencies of the particular SNP. Therefore, it is unpredictable whether the original populations of younger and older initially contained the same frequencies of alleles. If the polymorphism was regionally isolated, the event of mobility of the younger population would explain the variation of the polymorphisms within the populations. For example, if elderly Californians remain relatively settled within the region, and younger individuals migrate to the region, the frequencies of the polymorphism may vary. Without further analysis of the original older population of allele frequencies it is unclear how these frequencies have changed. In the event that the nucleotide is environmentally sensitive and has either been selected against. Furthermore, if the polymorphism is located within a region of the gene which is a hotspot and naturally mutates in an individuals life, frequencies of the variation would change over time and would not be a reliable predictor of mortality. Additionally, whether the change is in response to certain environmental causes, the presence of a variant G allele is not predictable. The specification does not analyze individuals who are deceased for the presence of various alleles. Had the specification demonstrated that deceased individuals contained more G alleles in conjunction with the instant study illustrating that young individuals had A, a more conclusive analysis may be drawn. The specification is silent with respect to any analysis of T or C.

The is no correlation supported for T and C nucleotides at position 2073 of SEQ ID NO: 1. It is unpredictable whether these mutations would also be associated with any type of disease.

The art is silent with respect to additional mutations within the subcellular localization of camp-dependant protein kinase and therefore, not well characterized as to how affect mortality or morbitiy.

Additionally, there is no indication of what meant by increased mortality. The specification has defined "mortaility" as the statistical likelihood that an organism will not survive a full predicted lifespan. The specification has not provided any indication that the individuals analyzed have not survived a full predicted lifespan. Moreover, it is unclear what the relative meaning of increased mortality encompasses since all individuals are predisposed to die.

With respect to Claim 44, directed to a cell comprising a nucleic acid that encodes a human AKAP10 variant protein or portion that exhibits a biological activity of the full length variant protein wherein the AKAP10 variant protein or portion thereof comprises valine at position corresponding to the position of amino acid residue 646 of SEQ ID NO: 2. The specification has provided a single human AKAP10 variant protein, namely a substitution at amino acid position 646 of SEQ ID NO: 2. The specification does not particular provide any additional variant proteins that exhibit a biological activity of the variant protein. The specification fails to provide any biological activity information for the variant protein to constitute a function, therefore, determining whether the portion exhibits biological activity has not been described. Therefore,

determining the function of the variant protein would require and constitute carry out further research to confirm a real world context of use.

As noted by Brenner v. Manson, 383 U.S. 519, 535-536 (1996), "Congress intended that no patents be granted on a chemical compound whose sole "utility" consists of its potential role as an object of use-testing...a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion". Therefore, in order to reasonably confirm a "real world" context of use for this nucleic acid, the skilled artisan would be required to carry out further research.

Claim Rejections - 35 USC § 112- Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-8, 11-20, 44-53, 69-71, 75 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112-Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 6-8, 11-18, 44, 47-50, 69-71, 75 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 6-8, 15-18 are drawn broadly to encompass any isolated nucleic acid which comprises at least 14, 30, or 50 contiguous nucleotides of SEQ ID NO: wherein the contiguous nucleotide include 5 contiguous nucleotides from position 2069-2077 of SEQ ID NO: 3. The claim as written minimally comprises 14, 30 or 50 contiguous nucleotides of SEQ ID NO: 3 embedded within a larger sequence. As noted by the art cited in rejections below, the instant specification has not described a representative number of members within this very large genus. There is actual reduction to practice of a single disclosed species, namely SEQ ID NO: 3. The genus of nucleic acids comprising at least 14, 30 or 50 contiguous nucleotides from SEQ ID NO: 3 encompasses splice variants of AKAP10-5, polymorphic sequences of AKAP10-5, a full length gene which contains the fragment and homologous sequences which have not been described. There is substantial variability among the species of DNA s encompassed within the scope of the claims because the claim is only drawn to a fragment of SEQ ID NO: 3 which may be embedded in alternative sequences.

Claims 11-14, 47-50, 69-71 is drawn to an oligonucleotides which comprises a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO: 1 or 3. The

specification defines "adjacent" as a position 5' to the sit of a SNP such that there could be unpaired nucleotides between the position and the site of the SNP (page 40, lines 14-16). Claim 69 is drawn to a solid support comprising a nucleic acid comprising a polymorphic region of an AKAP10 gene, wherein the polymorphic region comprises a nucleotide at a position corresponding to position 2073 of SEQ ID NO: 1 that is other than an A. As defined by the specification, a nucleic acid which "corresponds" to the nucleic acid may be of different length, such that the sequences are aligned and then the position that lines up with 2073 is identified (page 38-39). This does not require any particular sequence flanking the nucleotide "other than A." The claim encompasses any size nucleotide sequence, which hybridizes under any conditions upstream of position 2073 of SEQ ID NO: 1 or 3 or any sequence which "corresponds" to position 2073. Thus, the "corresponding" sequence does not require any particular similarity or identity with SEQ ID NO: 1 or 3. Moreover, Claim 13 requires that the primer hybridize immediately adjacent to a position corresponding to a position corresponding to position 2073. As discussed above, "corresponding" does not require that the sequence resemble SEQ ID NO: 1 or 3. Moreover, depending on the interpretation of the recitation "a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO: 1 or 3 of an AKAP10 allele..." the claim may lack description. Because it is unclear whether the claim is directed to a sequence of nucleotides that specifically hybridizes adjacent to an AKAP10 allele, the specification has only described a single allele within the scope of the claims. The description of this single variant is not representative of all

AKAP10 alleles. The nature of variants is such that the indication of a single variant allele is not representative of unknown alleles. The variant structures, in the present state of the art, of one variant does not provide guidance to the structure of others.

Claim 44 is directed to a cell comprising a nucleic acid that encodes a human AKAP10 variant protein or portion that exhibits a biological activity of the full length variant protein wherein the AKAP10 variant protein or portion thereof comprises valine at position corresponding to the position of amino acid residue 646 of SEQ ID NO: 2. The specification has described a single human AKAP10 variant protein, namely a substitution at amino acid position 646 of SEQ ID NO: 2. The specification does not particular provide any additional variant proteins that exhibit a biological activity of the variant protein. The specification fails to provide any biological activity information for the variant protein to constitute a function, therefore, determining whether the portion exhibits biological activity has not been described. Furthermore, the claim encompasses additional mutations, splice variants and transitions which have not been described in the instant specification. The nature of variants is such that the indication of a single variant allele is not representative of unknown alleles. The variant structures, in the present state of the art, of one variant does not provide guidance to the structure of others.

Claim 75 is drawn broadly to a primer consisting essentially of a nucleotide selected from SEQ ID NO: 8, 15, 19 and 20. The nucleic acid reads on any oligonucleotide which comprises SEQ ID NO: 8, 15, 19 and 20 which vary in length from 17-20 nucleotides. As discussed above, the partial structure embedded within a larger

sequence is not representative of the entire genus, as exemplified by the art rejections below.

Therefore, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 6-8, 11-18, 47-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 6-8, 15-16 are indefinite over the recitation "at least 14 or 16 contiguous nucleotides" because it is unclear whether the claim is drawn to at least 14 nucleotides or at least 16 nucleotides or alternatively whether the claim is drawn to at least 14 nucleotides or 16 nucleotides. Therefore, it is unclear the metes and bounds of the claims.

B) Claims 11-18, 47-50 are indefinite over the recitation "a sequence of nucleotides that specifically hybridizes adjacent to or at a polymorphic region spanning a position corresponding to position 2073 of SEQ ID NO: 1 or 3 of an AKAP10 allele..." because it is unclear whether the claim is directed to a sequence of nucleotides that specifically hybridizes adjacent to an AKAP10 allele or whether the claim is drawn to

requiring a sequence of nucleotides that specifically hybridizes adjacent to position 2073. It is noted that both the recitation adjacent and corresponding have been interpreted very broadly in commensurate scope with the definitions provided in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

10. Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Endege et al (US Pat. 6,262,334, July 17, 2001; filed August 1999).

Endege teaches a nucleic acid comprising 15 contiguous nucleotides of SEQ ID NO: 3, namely positions 2073-2087. These 15 contiguous nucleotides are 100% identical with nucleotides 498-484 of SEQ ID NO: 352. Therefore, Endege teaches an isolated nucleic acid comprising at least 14 contiguous nucleotides of SEQ ID NO: 3, wherein the contiguous nucleotides includes 5 contiguous nucleotides, namely 2070-

2077 of SEQ ID NO: 3. Therefore, Endege anticipates each limitation of the claimed invention.

11. Claim 6 is rejected under 35 U.S.C. 102(e) as being anticipated by Fleischmann et al (US Pat. 6,294,328, September 25, 2001; filed June 24, 1999).

Fleischmann et al. (herein referred to as Fleischmann) teaches a nucleic acid sequence from Mycobacterium tuberculosis. The nucleic acid of Fleischmann comprises 15 contiguous nucleotides of SEQ ID NO: 3, namely positions 2072-2086. These 15 contiguous nucleotides are 100% identical with nucleotides 1538363-1538349 of SEQ ID NO: 2. Therefore, Fleischmann teaches an isolated nucleic acid comprising at least 14 contiguous nucleotides of SEQ ID NO: 3, wherein the contiguous nucleotides includes 6 contiguous nucleotides, namely 2069-2077 of SEQ ID NO: 3. Therefore, Fleischmann anticipates each limitation of the claimed invention.

12. Claim 11-14, 69-71 are rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Pat. 5,474,796, filed December 12, 1995).

The claims, as written, are directed to a nucleic acid molecule comprising a sequence that specifically hybridizes adjacent to a polymorphic region corresponding to position 2073 of SEQ ID NO: 1 or 3. The specification defines “adjacent” as a position 5’ to the sit of a SNP such that there could be unpaired nucleotides between the position and the site of the SNP (page 40, lines 14-16). Claim 69 is drawn to a solid support comprising a nucleic acid comprising a polymorphic region of an AKAP10 gene, wherein the polymorphic region comprises a nucleotide at a position corresponding to

position 2073 of SEQ ID NO: 1 that is other than an A. As defined by the specification, a nucleic acid which "corresponds" to the nucleic acid may be of different length, such that the sequences are aligned and then the position that lines up with 2073 is identified. This does not require any particular sequence flanking the nucleotide "other than A." The limitations of Claim 13 do not require any particular sequence because the claim also recites "corresponding" such that the 5' sequence may not resemble SEQ ID NO: 3.

Brennan teaches a microarray comprising every possible 10-mer. Since the claims are broadly drawn to generic claims referring to any nucleic acid, of any length and of any sequence, Brennan, having taught every 10 mer anticipates the claims.

13. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Birren et al. (Genbank Accession Number AC005730, October 1998).

The claim is directed to a primer consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, 15, 19 and 20. Consisting essentially of has been interpreted broadly as "comprising." It is noted that the recitation "primer" has been given no weight for the intended use. The specification specifically teaches that primers can be 10, 20, 30, 50, 100 or more nucleotides in length, i.e. not specifically limiting the length of a primer.

Birren et al. (herein referred to as Birren) teaches a nucleic acid clone from chromosome 17 which comprises all 18 nucleotides of SEQ ID NO: 20. Nucleotides 1-

18 of SEQ ID NO: 20 are identical to positions 129,582-129,599 of the chromosome 17 nucleic acid. Therefore, Birren teaches a nucleic acid comprising SEQ ID NO: 20 as required by the instant claim.

14. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Genbank Accession Number AA331406, April 1997).

The claim is directed to a primer consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, 15, 19 and 20. Consisting essentially of has been interpreted broadly as "comprising." It is noted that the recitation "primer" has been given no weight for the intended use. The specification specifically teaches that primers can be 10, 20, 30, 50, 100 or more nucleotides in length, i.e. not specifically limiting the length of a primer.

Adams teaches a nucleic acid from an embryo, 8 week I Homo sapiens cDNA. The nucleic acid comprises all 19 nucleotides of SEQ ID NO: 19. Nucleotides 1-19 of SEQ ID NO: 19 are identical to positions 45-27 of the human nucleic acid. Therefore, Adams teaches a nucleic acid comprising SEQ ID NO: 19 as required by the instant claim.

15. Claim 75 is rejected under 35 U.S.C. 102(b) as being anticipated by Adams et al. (Genbank Accession Number AA349877, April 1997).

The claim is directed to a primer consisting essentially of nucleotide sequences selected from the group consisting of SEQ ID NO: 8, 15, 19 and 20. Consisting

essentially of has been interpreted broadly as "comprising." It is noted that the recitation "primer" has been given no weight for the intended use. The specification specifically teaches that primers can be 10, 20, 30, 50, 100 or more nucleotides in length, i.e. not specifically limiting the length of a primer.

Adams teaches a nucleic acid from an infant brain Homo sapiens cDNA. The nucleic acid comprises all 18 nucleotides of SEQ ID NO: 15. Nucleotides 1-18 of SEQ ID NO: 19 are identical to positions 198-181 of the human nucleic acid. Therefore, Adams teaches a nucleic acid comprising SEQ ID NO: 15 as required by the instant claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

16. Claims 47-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brennan (US Pat. 5,474,796, filed December 12, 1995) in view of Ahern (The Scientist, Vol 9, No. 15, page 20, July 1995).

The claims, as written, are directed to a nucleic acid molecule comprising a sequence that specifically hybridizes adjacent to a polymorphic region corresponding to position 2073 of SEQ ID NO: 1 or 3. The specification defines "adjacent" as a position 5' to the sit of a SNP such that there could be unpaired nucleotides between the

position and the site of the SNP (page 40, lines 14-16). Claim 69 is drawn to a solid support comprising a nucleic acid comprising a polymorphic region of an AKAP10 gene, wherein the polymorphic region comprises a nucleotide at a position corresponding to position 2073 of SEQ ID NO: 1 that is other than an A. As defined by the specification, a nucleic acid which "corresponds" to the nucleic acid may be of different length, such that the sequences are aligned and then the position that lines up with 2073 is identified. This does not require any particular sequence flanking the nucleotide "other than A." The limitations of Claim 13 do not require any particular sequence because the claim also recites "corresponding" such that the 5' sequence may not resemble SEQ ID NO: 3.

Brennan teaches a microarray comprising every possible 10-mer. Since the claims are broadly drawn to generic claims referring to any nucleic acid, of any length and of any sequence, Brennan, having taught every 10 mer anticipates the claims.

Brennan does not specifically teach packaging the nucleic acid in a kit.

However, Ahern teaches reagent kits offer scientists good return on investment. Ahern teaches kits save time and money because the kits already comes prepared.

Therefore, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the invention was made to have modified the teachings of Brennan with the teachings of Ahern to incorporate the necessary reagents into a packaged kit. The ordinary artisan would have been motivated to have packaged the primers, probes, and

reagents of Brennan into a kit, as taught by Ahern for the express purpose of saving time and money.

Conclusion

17. No claims allowable.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
May 1, 2003

JEHANNE SOUAYA
PATENT EXAMINER

Jehanne Souaya
5/1/03